

US009993231B2

(12) **United States Patent**
Costello et al.

(10) **Patent No.:** **US 9,993,231 B2**
(45) **Date of Patent:** **Jun. 12, 2018**

(54) **DEVICES, SYSTEMS, AND METHODS FOR NAVIGATING A BIOPSY TOOL TO A TARGET LOCATION AND OBTAINING A TISSUE SAMPLE USING THE SAME**

USPC 600/562, 564, 565, 566, 567, 568;
606/167
See application file for complete search history.

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(56) **References Cited**

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U.S. PATENT DOCUMENTS

3,732,858 A * 5/1973 Banko A61B 10/0266
600/566

3,844,272 A 10/1974 Banko
3,882,849 A 5/1975 Jamshidi

(Continued)

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FOREIGN PATENT DOCUMENTS

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 775 days.

EP 2018112 A2 1/2009
WO 2007109418 A2 9/2007

(Continued)

(21) Appl. No.: **14/488,611**

OTHER PUBLICATIONS

(22) Filed: **Sep. 17, 2014**

International Search Report from corresponding PCT/US2014/058442 dated Dec. 26, 2014.

(65) **Prior Publication Data**

US 2015/0141869 A1 May 21, 2015

(Continued)

Related U.S. Application Data

Primary Examiner — May Abouelela

(60) Provisional application No. 61/906,771, filed on Nov. 20, 2013.

(57) **ABSTRACT**

(51) **Int. Cl.**

A61B 10/00 (2006.01)
A61B 10/02 (2006.01)
A61B 10/04 (2006.01)
A61B 34/20 (2016.01)

A biopsy tool includes an elongated flexible body, a sensor assembly, and a screw member. The sensor assembly is disposed within the elongated flexible body towards the distal end thereof. The sensor assembly includes a location sensor(s) configured to enable detection of a location of the sensor assembly. The screw member is coupled to the distal end of elongated flexible body, extends distally from the elongated flexible body, and is positioned distally of the sensor assembly. The screw member defines a helical configuration having a hollow interior and is configured for simultaneous rotation relative to tissue and advancement into tissue to obtain a tissue sample.

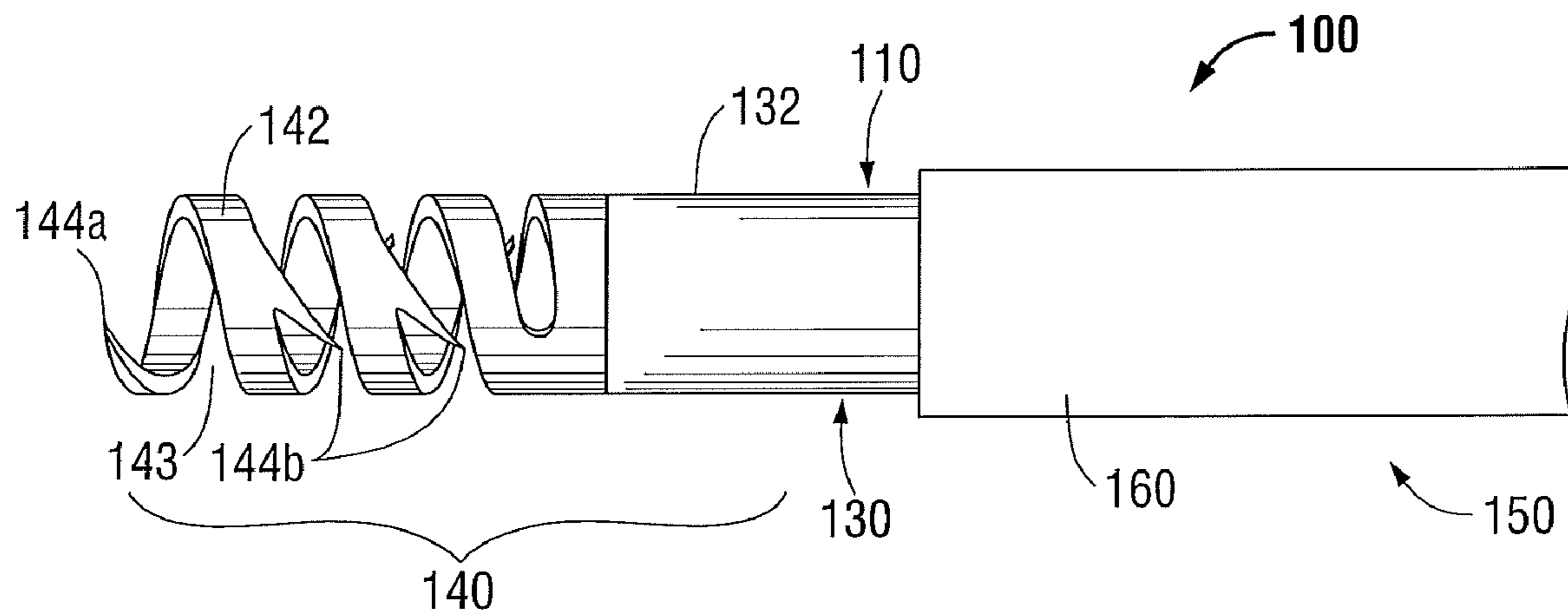
(52) **U.S. Cl.**

CPC **A61B 10/0266** (2013.01); **A61B 10/04** (2013.01); **A61B 2010/0208** (2013.01); **A61B 2034/2051** (2016.02)

(58) **Field of Classification Search**

CPC **A61B 17/320758**; **A61B 2018/1861**; **A61B 10/0266**; **A61B 1/2676**

19 Claims, 8 Drawing Sheets



(56)

References Cited

U.S. PATENT DOCUMENTS

4,111,207 A 9/1978 Seiler, Jr.
 4,177,797 A 12/1979 Baylis et al.
 4,662,869 A 5/1987 Wright
 4,682,606 A * 7/1987 DeCaprio A61B 10/0266
 600/567
 4,702,260 A 10/1987 Wang
 4,708,147 A 11/1987 Haaga
 4,745,919 A * 5/1988 Bundy A61B 17/3207
 600/564
 4,935,025 A * 6/1990 Bundy A61B 10/04
 600/564
 5,018,530 A * 5/1991 Rank A61B 17/3403
 600/435
 5,211,651 A * 5/1993 Reger A61B 17/32075
 606/159
 5,226,909 A * 7/1993 Evans A61B 17/32078
 604/22
 5,251,641 A 10/1993 Xavier
 5,437,266 A * 8/1995 McPherson A61B 17/0218
 600/217
 5,615,690 A 4/1997 Giurtino et al.
 5,807,282 A 9/1998 Fowler
 6,083,237 A * 7/2000 Huitema A61B 10/0233
 600/567
 6,162,214 A 12/2000 Mueller et al.
 6,302,903 B1 * 10/2001 Mulier A61B 18/1477
 606/41
 6,371,928 B1 * 4/2002 Mcfann A61B 17/221
 600/434
 6,451,036 B1 * 9/2002 Heitzmann A61B 17/32075
 606/159
 6,709,408 B2 3/2004 Fisher
 6,743,245 B2 6/2004 Lobdell
 6,773,443 B2 8/2004 Truwit et al.
 6,872,185 B2 3/2005 Fisher
 6,890,309 B2 5/2005 Fisher
 6,908,440 B2 6/2005 Fisher
 6,981,949 B2 1/2006 Hibner et al.
 7,189,206 B2 3/2007 Quick et al.
 7,555,330 B2 6/2009 Gilboa et al.
 7,969,143 B2 6/2011 Gilboa

7,998,062 B2 8/2011 Gilboa
 8,241,225 B2 8/2012 Seiger et al.
 8,262,585 B2 9/2012 Thompson et al.
 8,343,072 B2 1/2013 Bacon et al.
 8,343,073 B2 1/2013 Miller
 8,506,503 B2 8/2013 Fritscher-Ravens et al.
 8,532,748 B2 9/2013 Leimbach et al.
 8,568,334 B2 10/2013 Field et al.
 8,611,984 B2 12/2013 Greenburg et al.
 8,641,640 B2 2/2014 Lubock et al.
 8,784,333 B2 7/2014 Corvi et al.
 8,821,411 B2 9/2014 Berberich
 8,858,461 B2 10/2014 Persat
 9,155,527 B2 * 10/2015 Vetter A61B 10/0266
 9,463,001 B2 * 10/2016 Vetter A61B 10/0266
 2002/0143270 A1 10/2002 Miller
 2003/0114773 A1 * 6/2003 Janssens A61B 10/0233
 600/564
 2009/0018468 A1 1/2009 Janssens
 2009/0284255 A1 11/2009 Zur
 2010/0016757 A1 1/2010 Greenburg et al.
 2010/0241028 A1 9/2010 Johnson et al.
 2013/0096459 A1 * 4/2013 Vetter A61B 10/06
 600/567
 2013/0223702 A1 8/2013 Holsing et al.
 2013/0331733 A1 12/2013 Plishka et al.
 2014/0128770 A1 * 5/2014 Vetter A61B 10/06
 600/566
 2014/0358029 A1 * 12/2014 Vetter A61B 10/0266
 600/567

FOREIGN PATENT DOCUMENTS

WO 2011004776 A1 1/2011
 WO 2012068315 A1 5/2012

OTHER PUBLICATIONS

European Search Report dated Jun. 23, 2017, issued in EP Application No. 14863619.
 Japanese Office Action dated Aug. 17, 2018, in Japanese Appln. No. 2016531979.

* cited by examiner

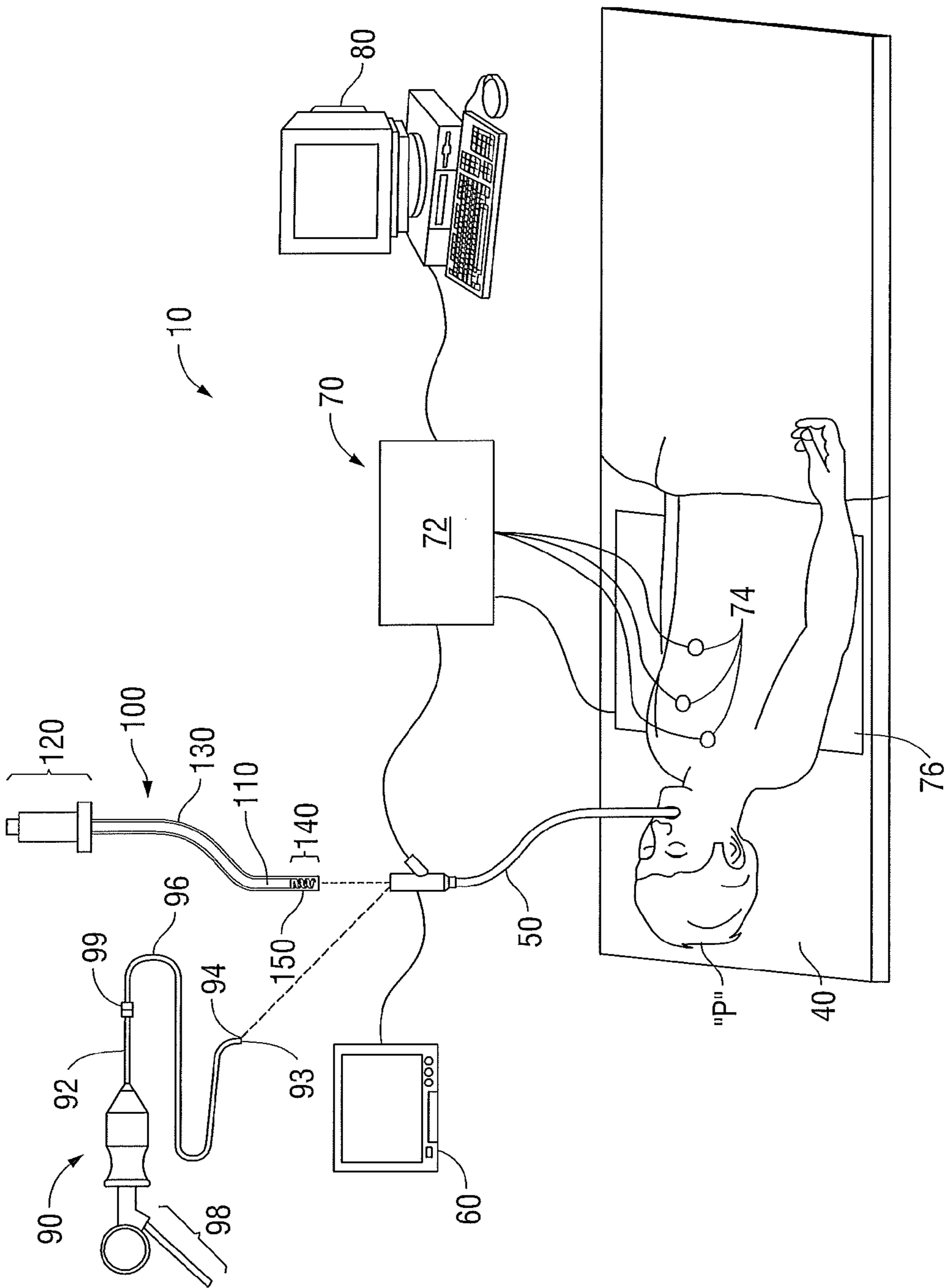


FIG. 1

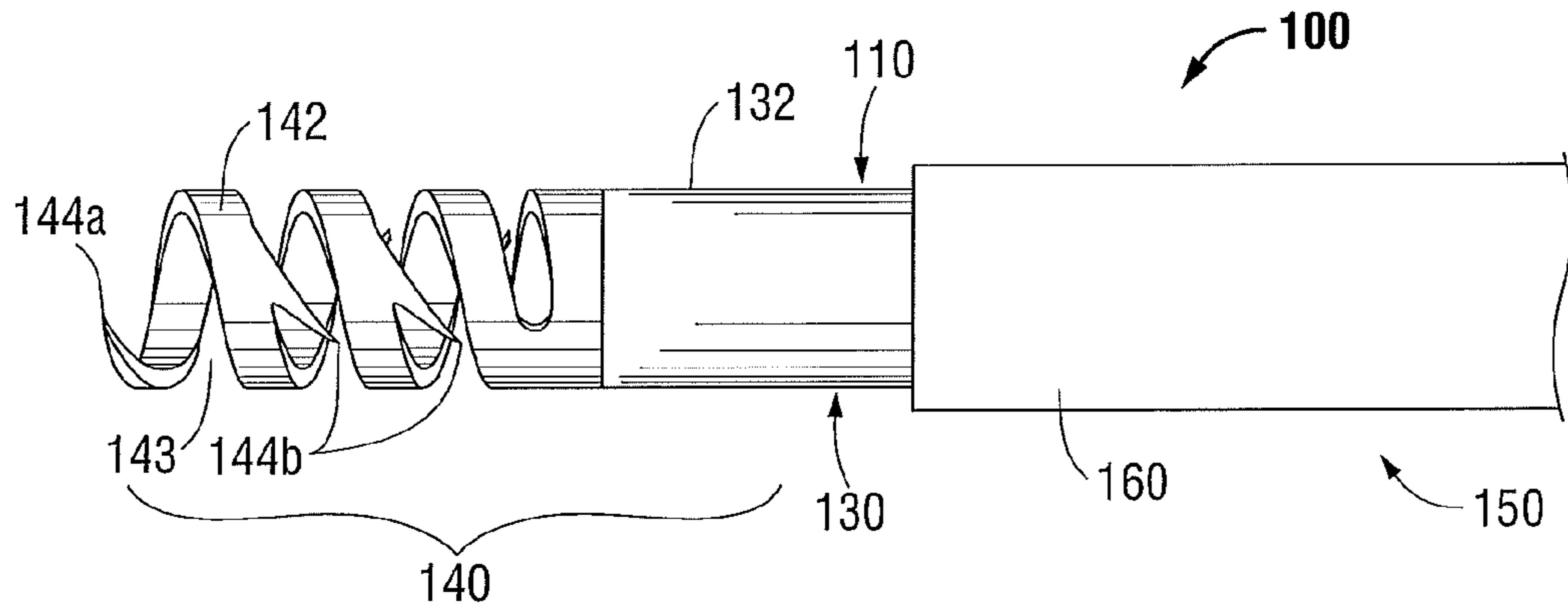


FIG. 2

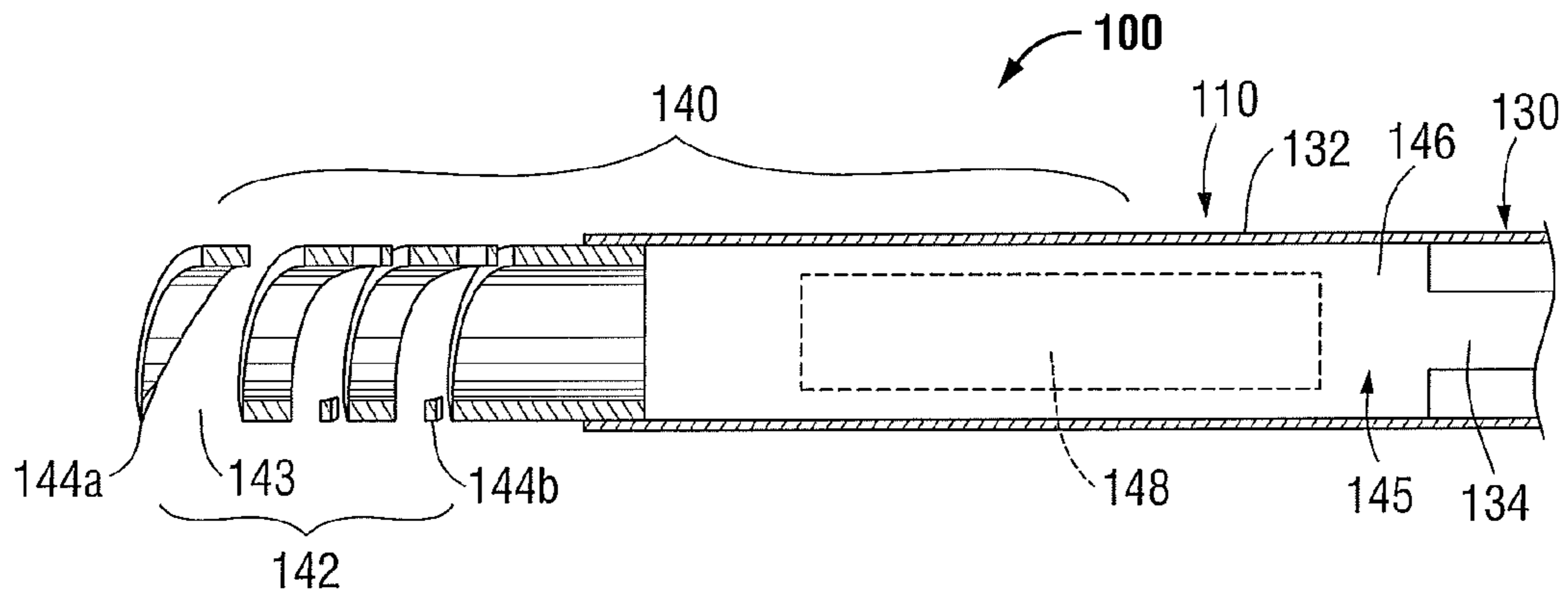


FIG. 3

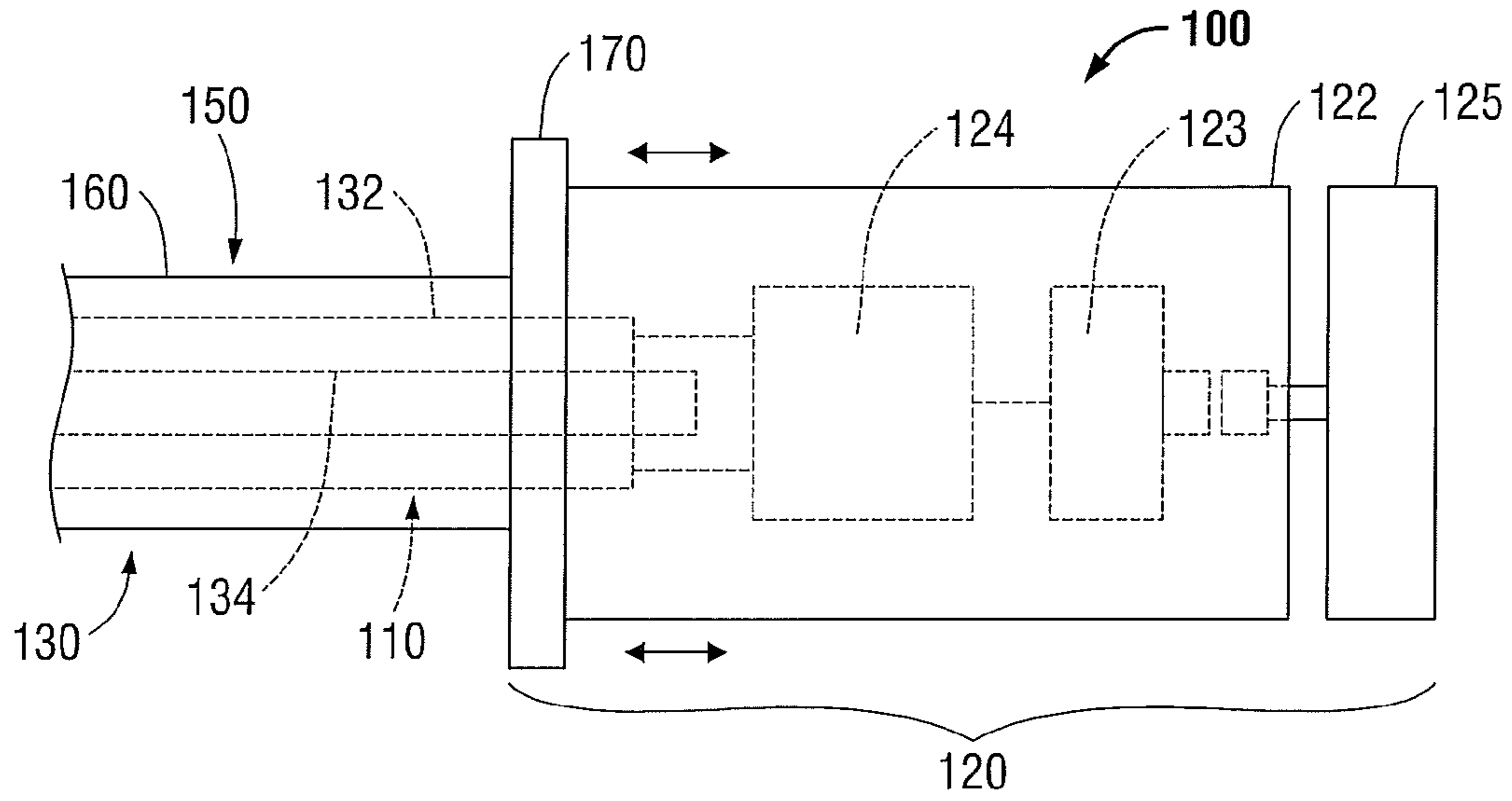


FIG. 4A

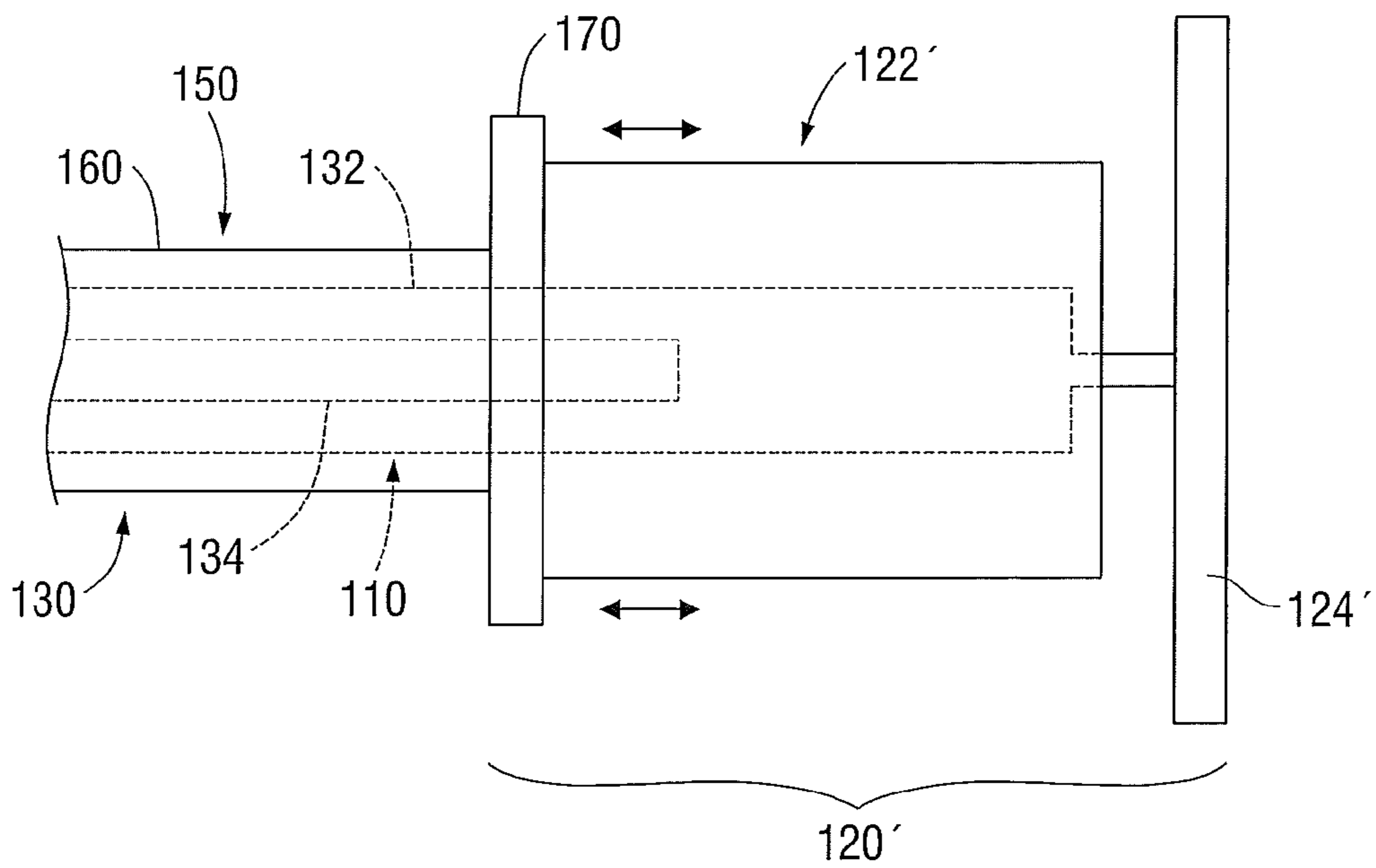


FIG. 4B

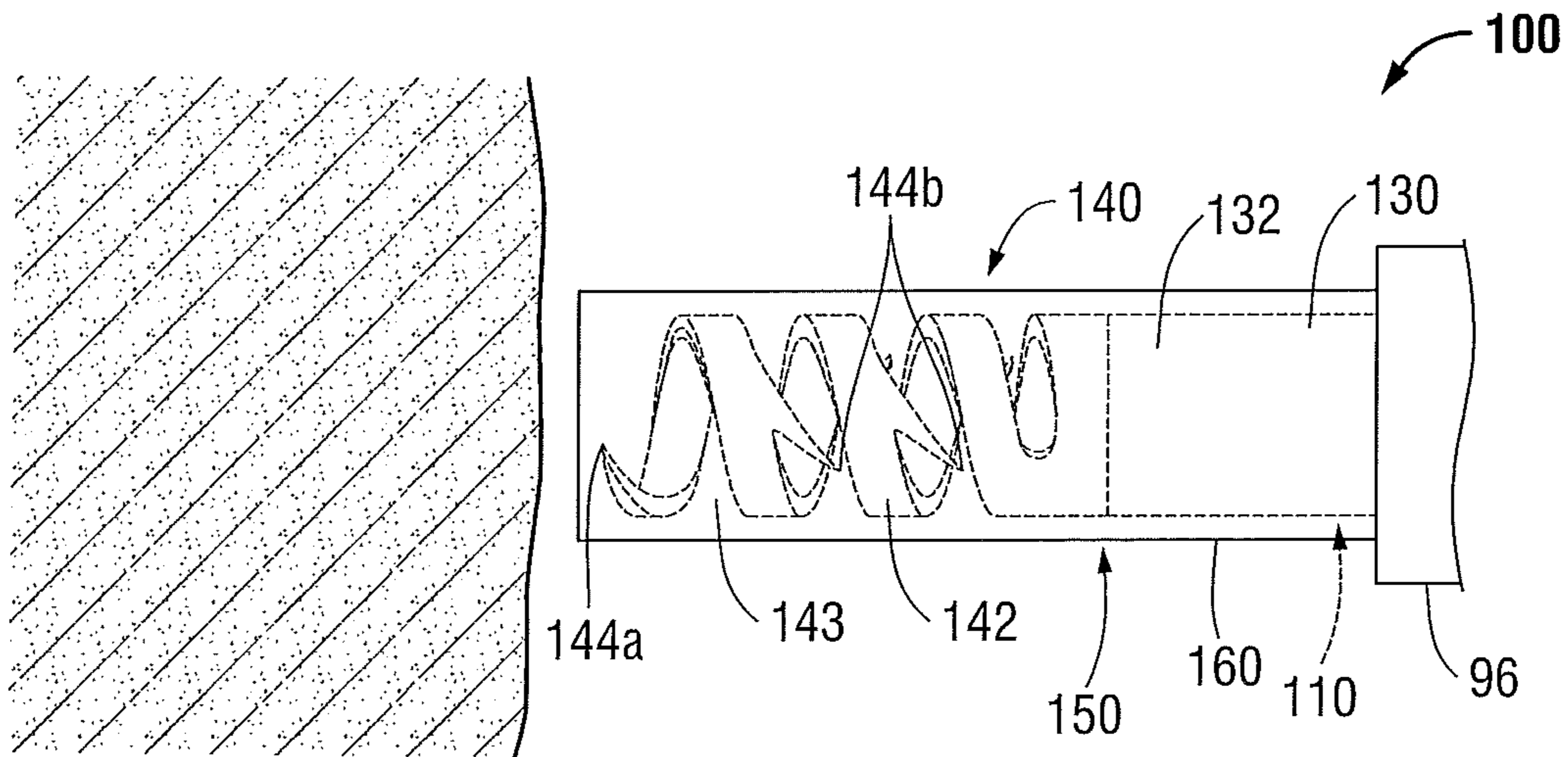


FIG. 5A

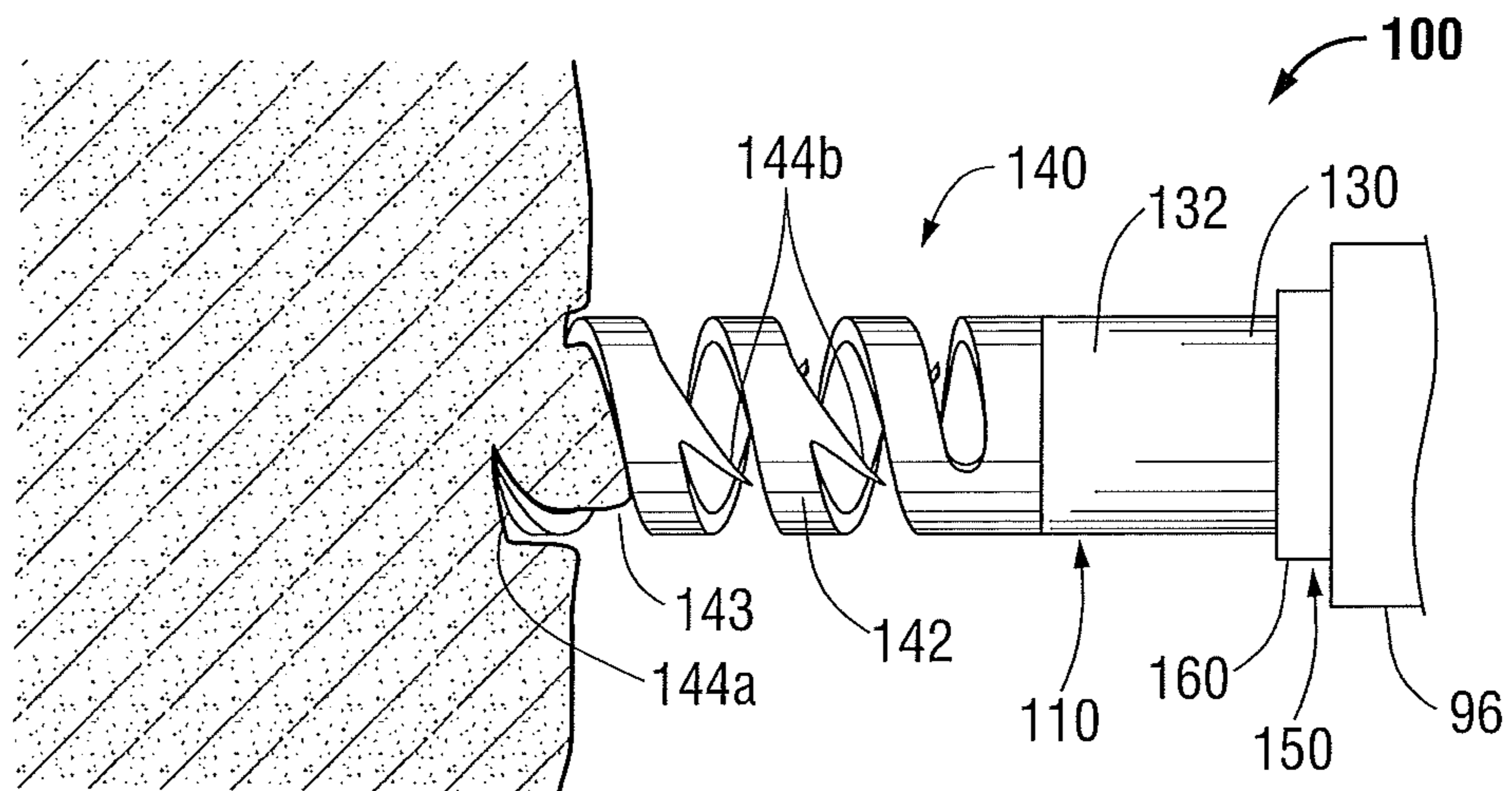


FIG. 5B

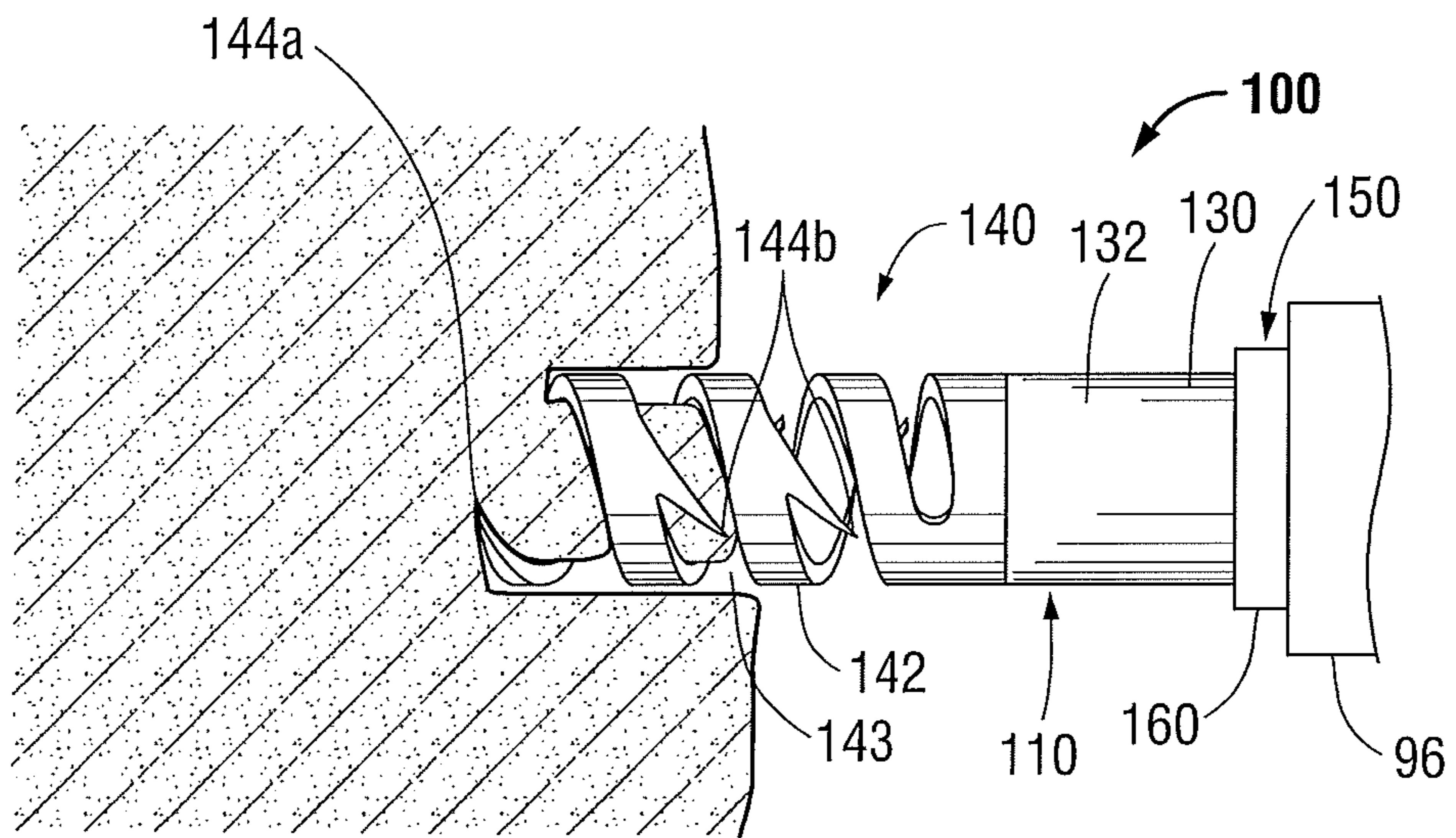


FIG. 5C

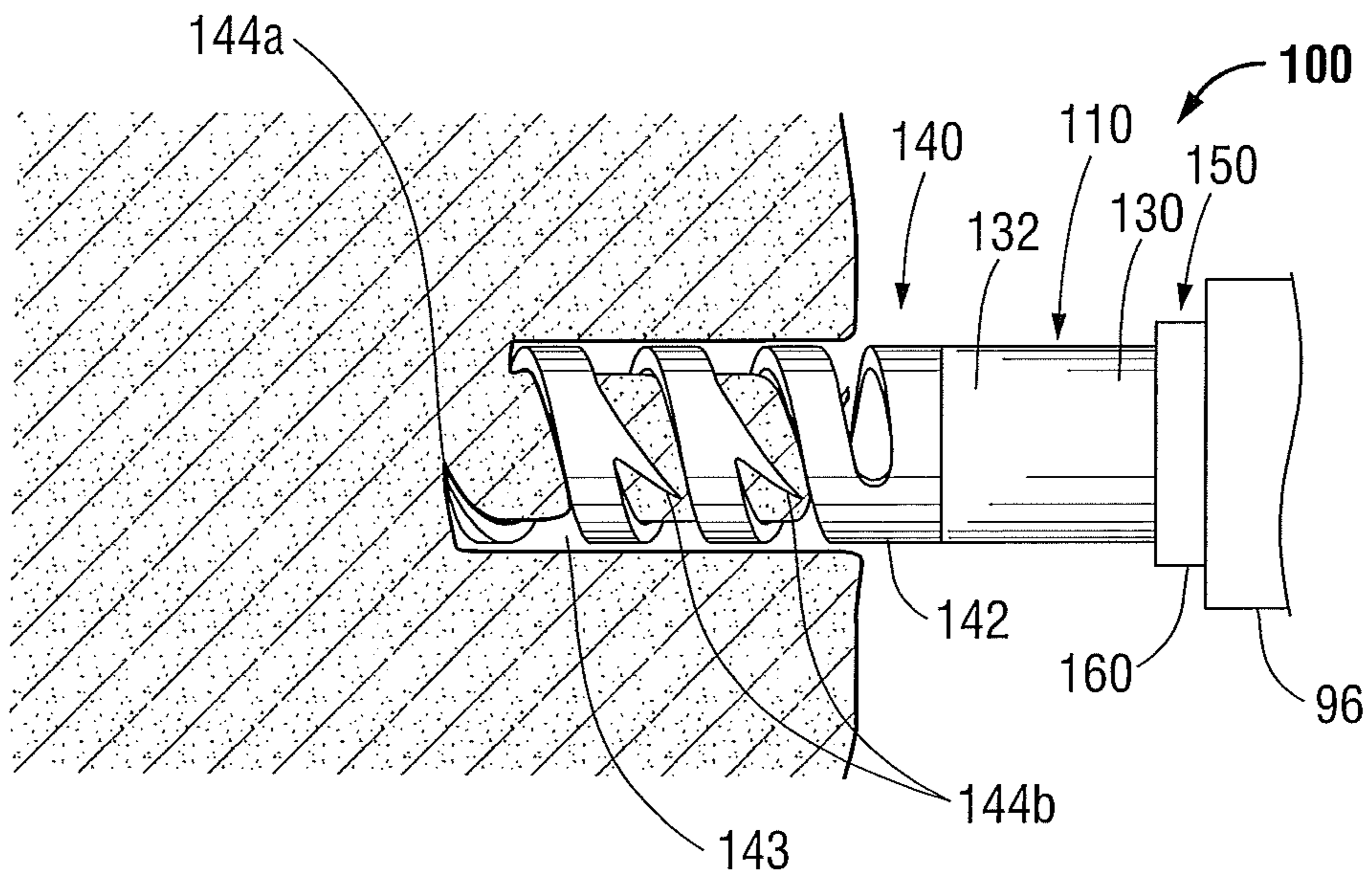


FIG. 5D

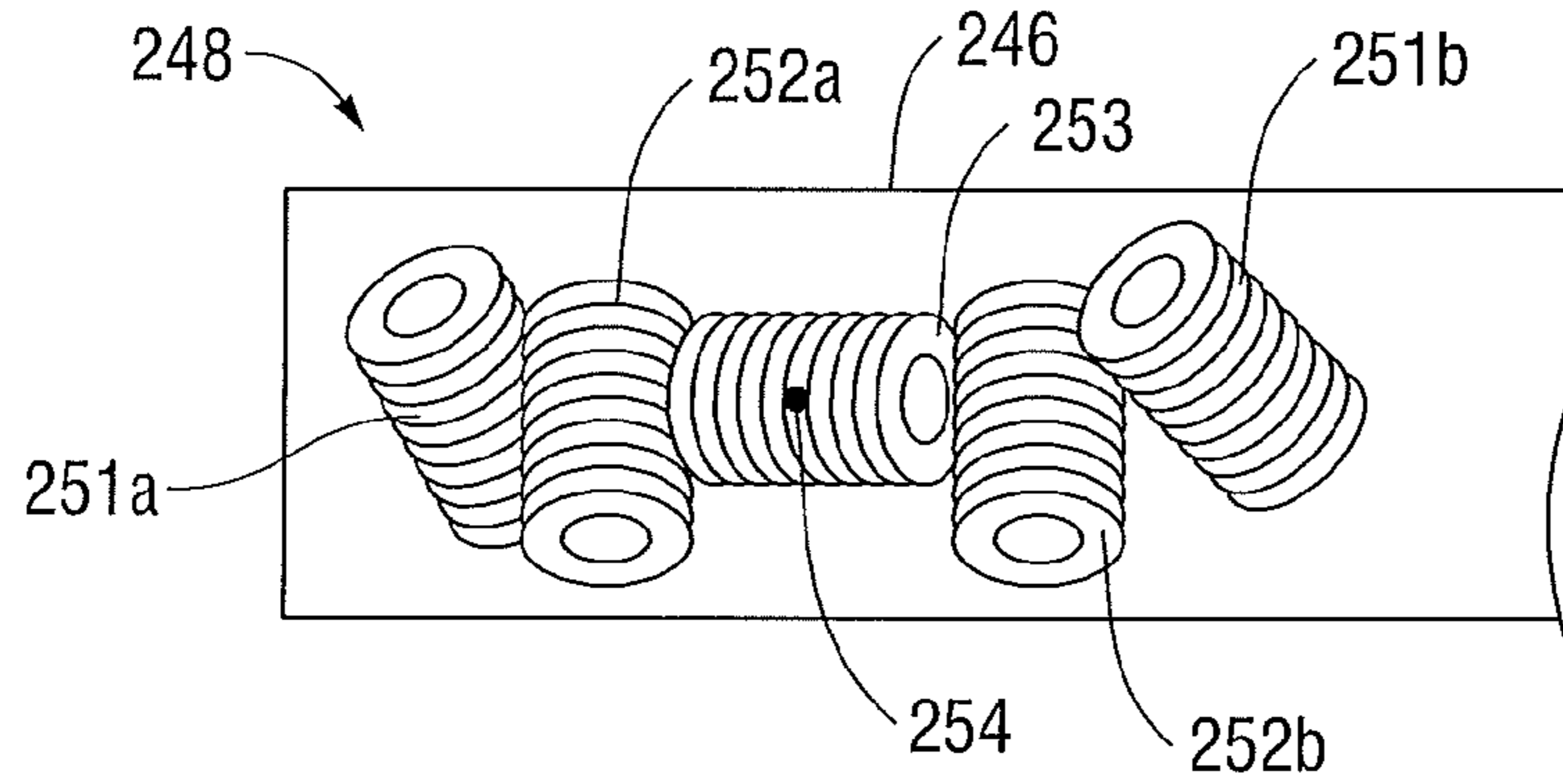


FIG. 6

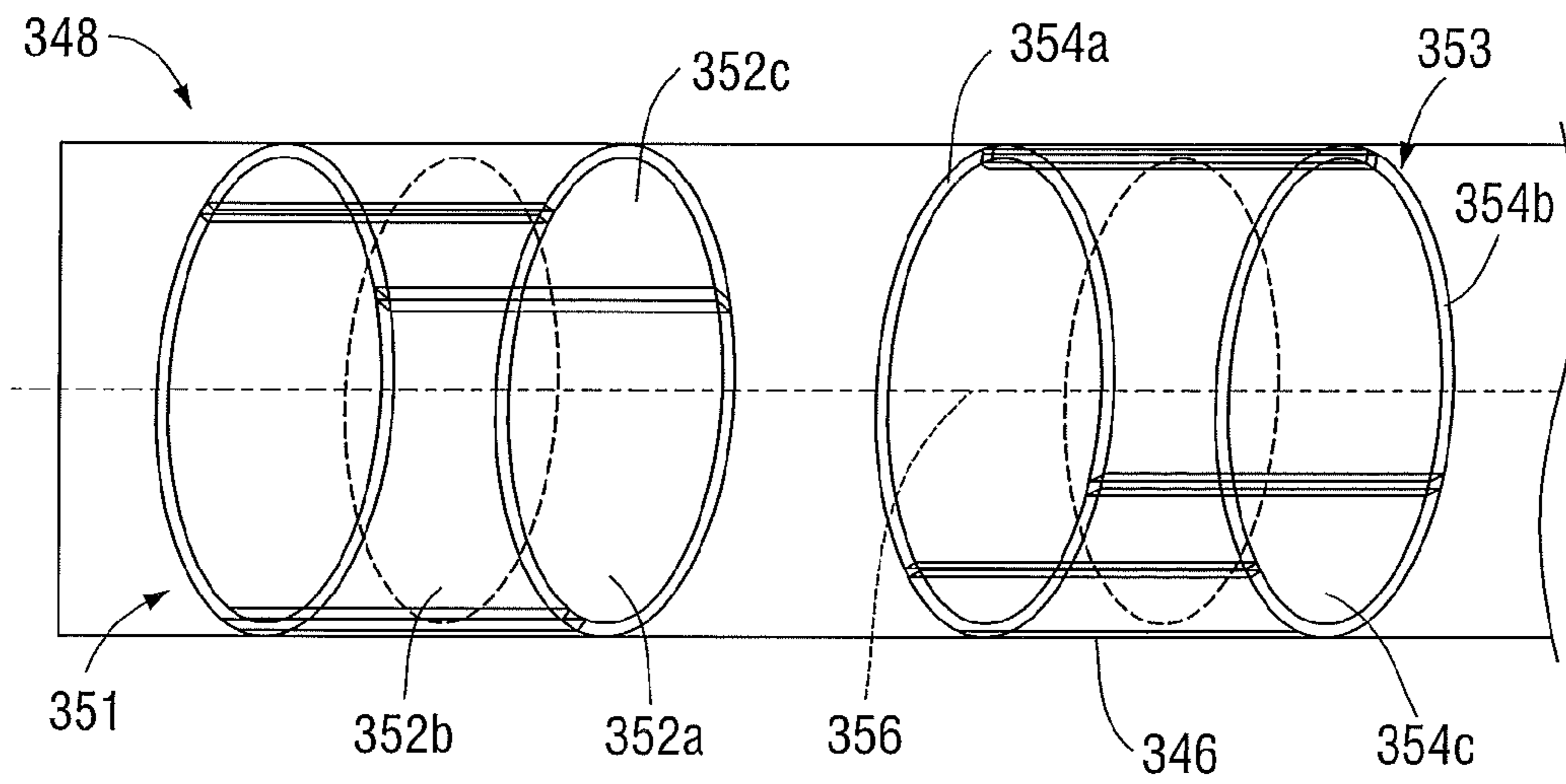


FIG. 7

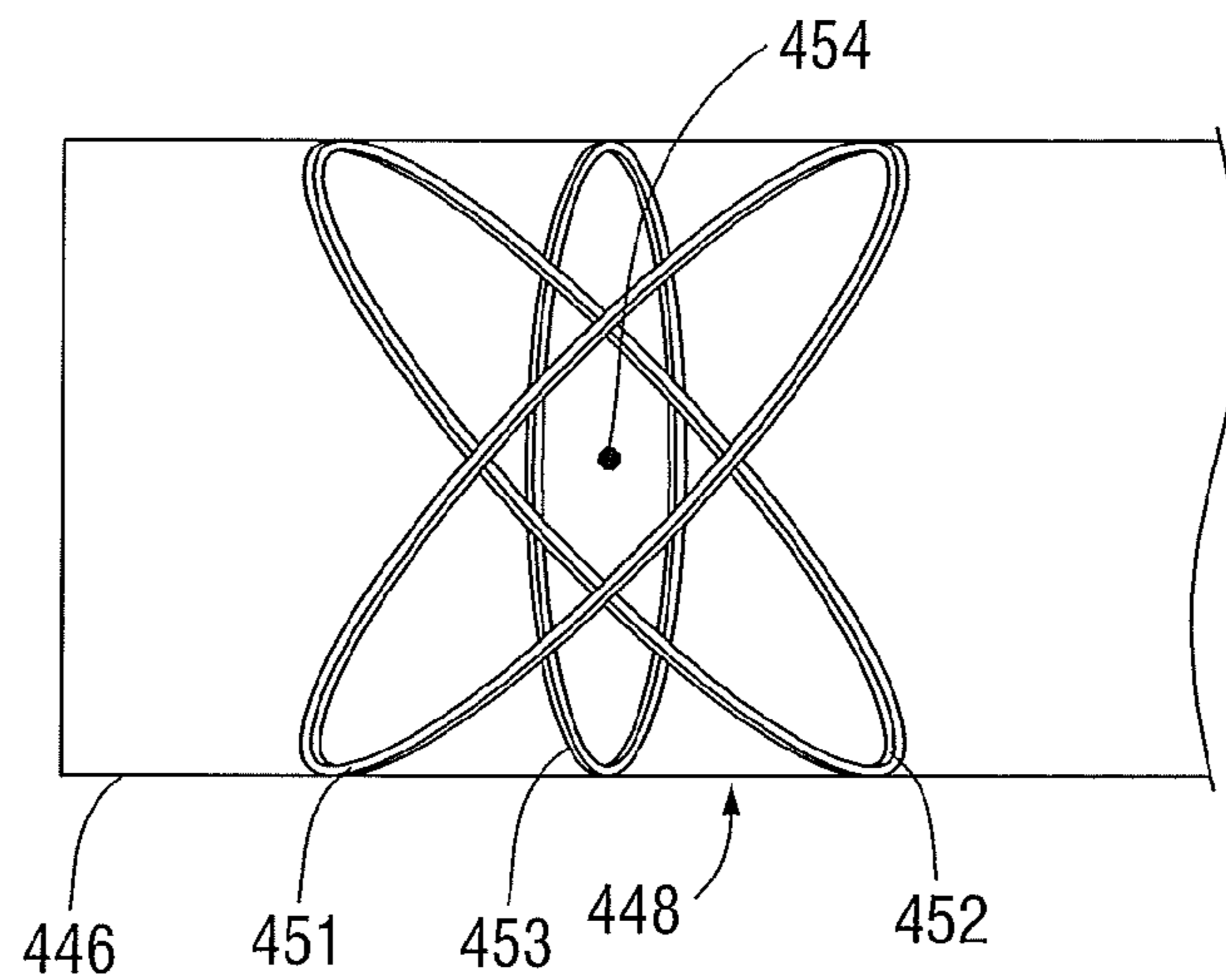


FIG. 8

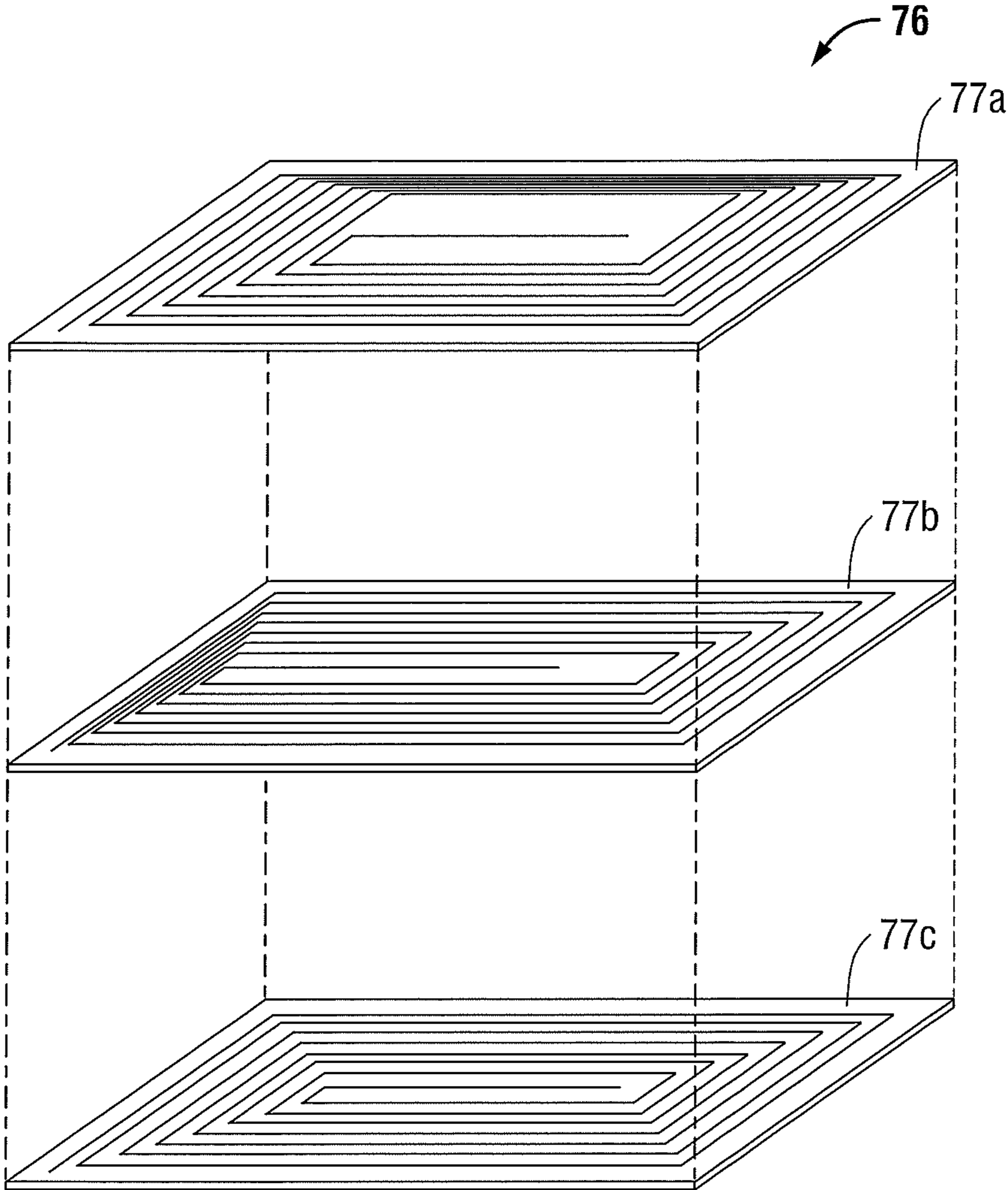


FIG. 9

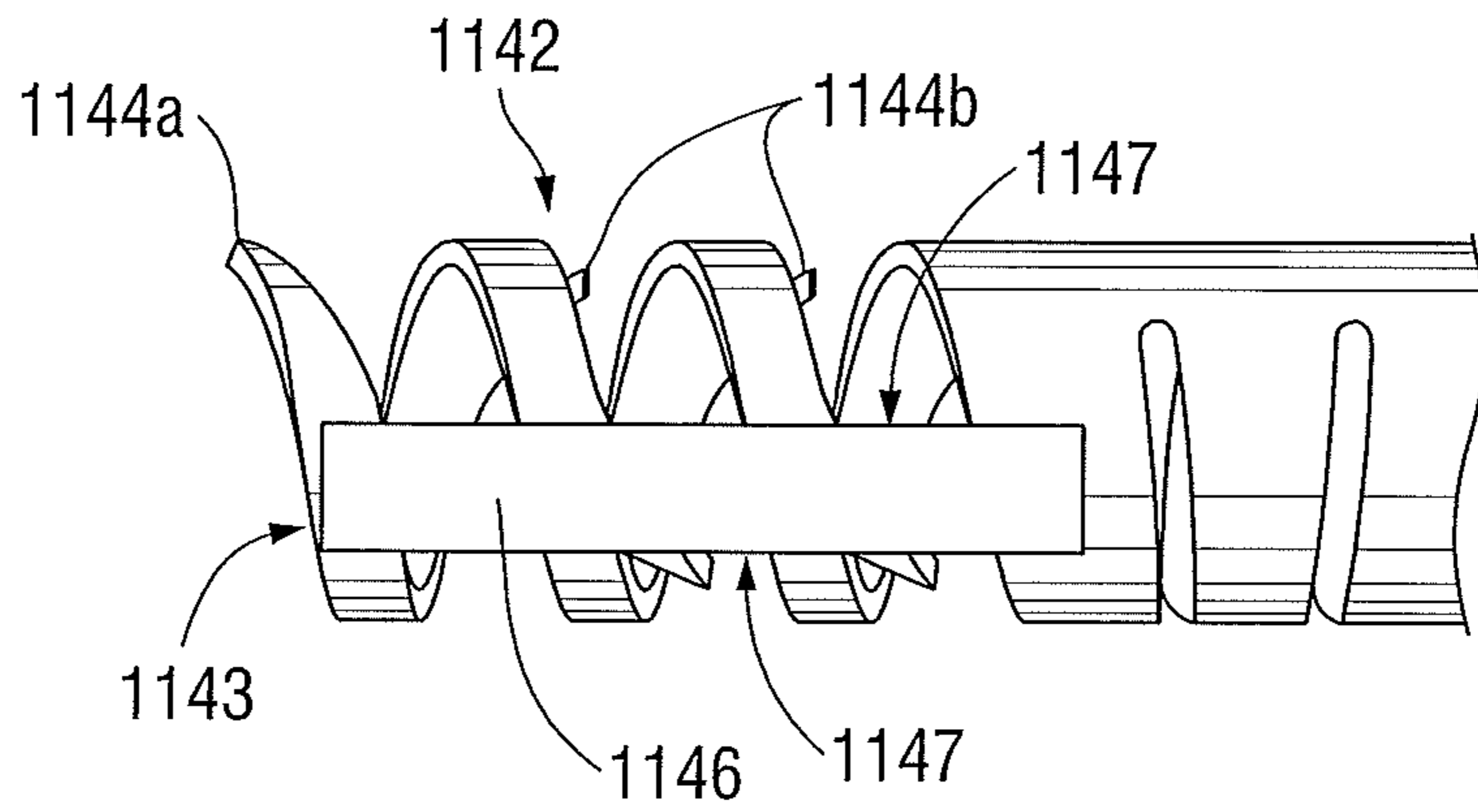


FIG. 10A

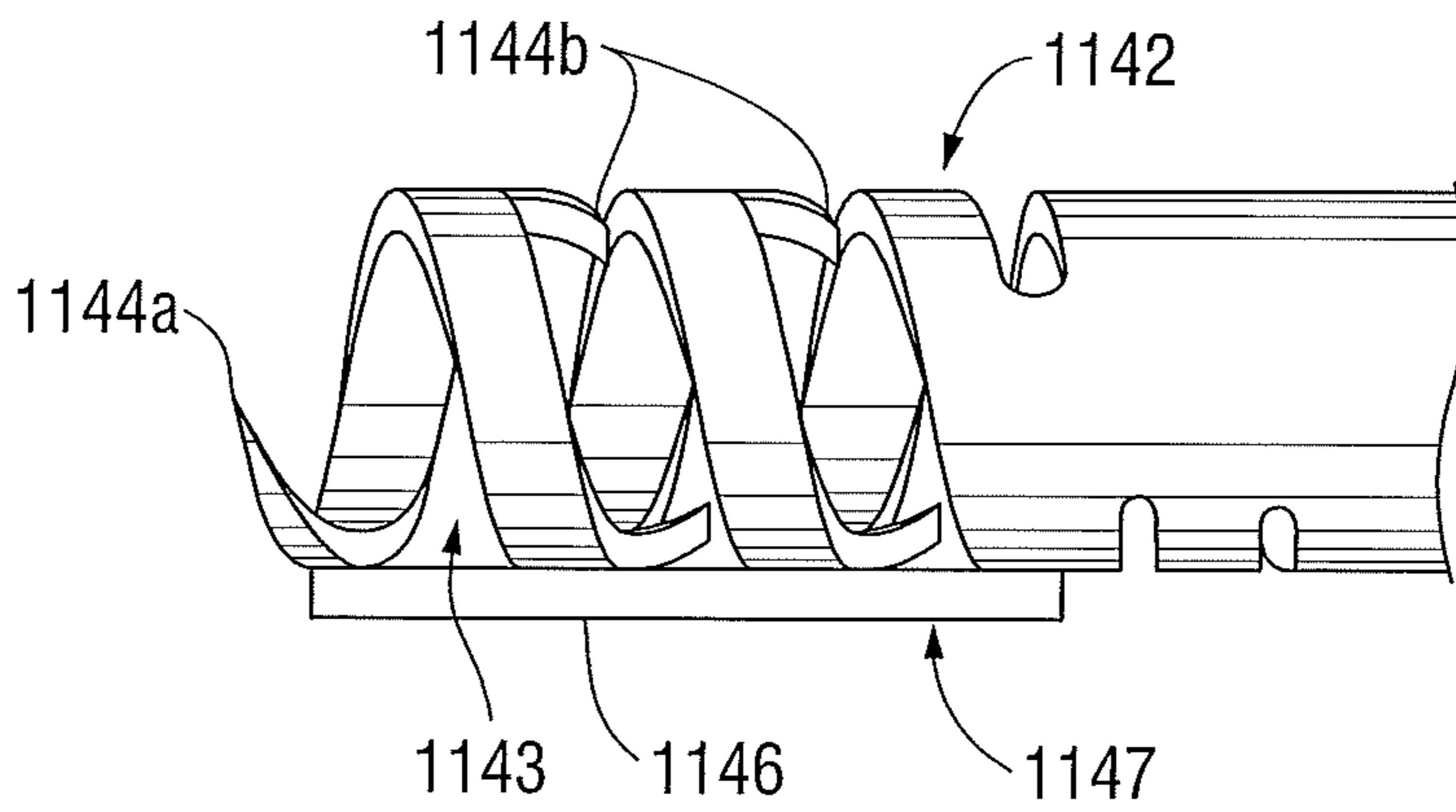


FIG. 10B

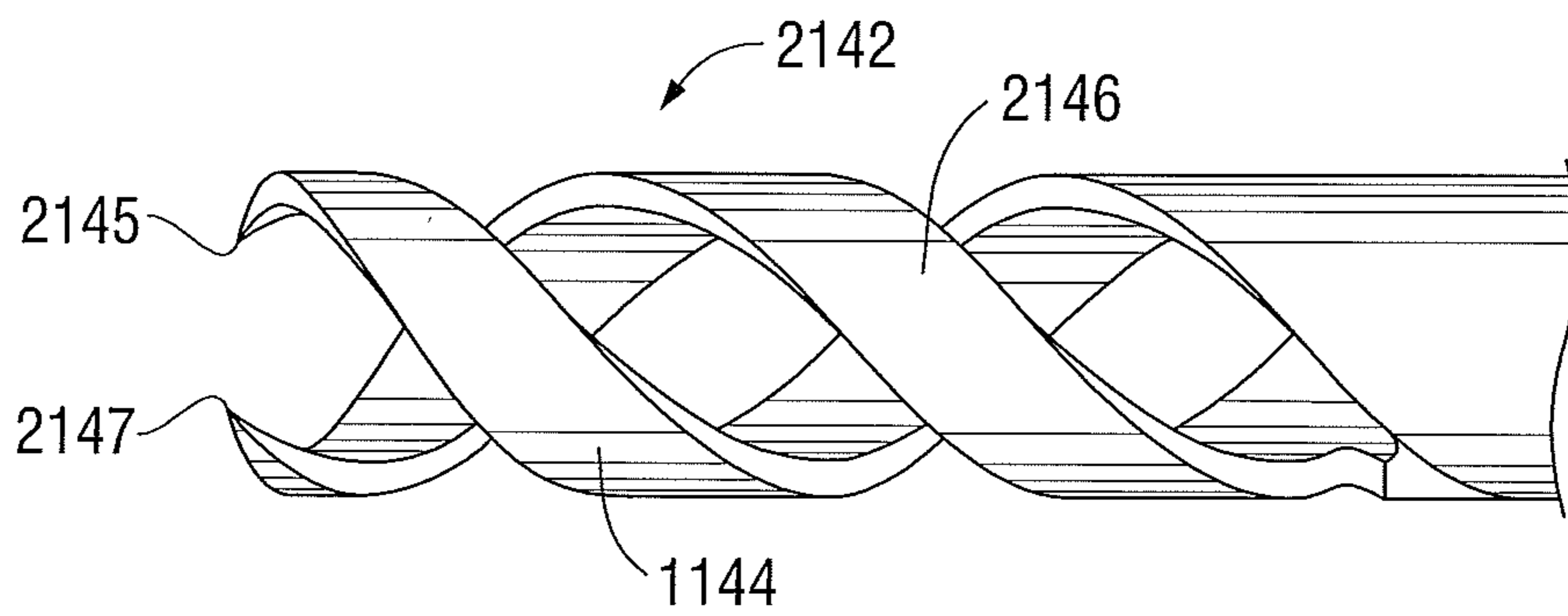


FIG. 11

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**DEVICES, SYSTEMS, AND METHODS FOR
NAVIGATING A BIOPSY TOOL TO A
TARGET LOCATION AND OBTAINING A
TISSUE SAMPLE USING THE SAME**

CROSS-REFERENCE TO RELATED
APPLICATIONS

This application claims the benefit of, and priority to, U.S. Provisional Patent Appln. No. 61/906,771, filed on Nov. 20, 2013, the entire contents of which are incorporated herein by reference.

BACKGROUND

Technical Field

The present disclosure relates to biopsy sampling and, more particularly, to devices, systems, and methods for navigating a biopsy tool to a target location and obtaining a tissue sample using the biopsy tool.

Description of Related Art

A bronchoscope is inserted into a patient's airways through the patient's nose or mouth. A typical bronchoscope includes an elongated flexible tube having an illumination assembly for illuminating the region distal to the bronchoscope's tip, an imaging assembly for providing a video image from the bronchoscope's tip, and a working channel through which instruments, e.g., diagnostic instruments such as biopsy tools and/or therapeutic instruments such as ablation probes, can be inserted.

Bronchoscopes are limited in how far they may be advanced through the airways due to their size. Where the bronchoscope is too large to reach a target location deep in the lungs, a locatable guide ("LG") enveloped by a sheath is often utilized to navigate from the end of the bronchoscope to the target location. That is, the LG, together with a navigation system, enables the position and orientation of the LG to be tracked as the LG is advanced through the airways.

In use, the LG/sheath combination is inserted through the working channel of the bronchoscope and into the patient's airways. Once the LG has been navigated to the target location, aided by the position and orientation tracking provided by the navigation system, the LG is retracted through the sheath, leaving the sheath in position. With the LG retracted, the sheath is often referred to as an extended working channel ("EWC") because it effectively functions as an extension of the working channel of the bronchoscope.

Once the LG has been retracted from the EWC, the EWC may be used as an avenue for guiding working tools, e.g., biopsy tools, ablation probes, etc., to the target location. However, once the LG is removed from the EWC, tracking is no longer provided and, thus, the operator is operating blind, relying on the EWC to remain fixed at the target location. Repositioning of the working tool at the target location is likewise required to be performed without guidance.

SUMMARY

As used herein, the term "distal" refers to the portion that is being described which is further from a user, while the term "proximal" refers to the portion that is being described which is closer to a user. Further, to the extent consistent, any of the aspects and features detailed herein may be used in conjunction with any or all of the other aspects and features detailed herein.

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Provided in accordance with the present disclosure is a biopsy tool including an elongated flexible body, a sensory assembly, and a screw member. The sensor assembly is disposed within the elongated flexible body towards the distal end of the elongated flexible body. The sensor assembly includes at least one location sensor configured to enable detection of a location of the sensor assembly within a patient's airways. The screw member is coupled to the distal end of the elongated flexible body, extends distally from the elongated flexible body, and is positioned distally of the sensor assembly. The screw member defines a helical configuration having a hollow interior and is configured for simultaneous rotation relative to tissue and advancement into tissue to obtain a tissue sample within the hollow interior.

In aspects, the biopsy tool further includes a proximal handle portion coupled to a proximal end of the elongated flexible body. The proximal handle portion includes a housing having a drive motor disposed within the housing. The drive motor is configured to rotate the screw member.

In aspects, the proximal handle portion further includes an actuator configured for selectively activating the drive motor. The proximal handle portion may further include a battery disposed within the housing and configured such that actuation of the actuator completes an electrical circuit between the battery and the drive motor to activate the drive motor.

In aspects, the proximal handle portion is configured for manual manipulation to drive rotation of the screw member. In aspects, the screw member is rigid, e.g., made of stainless steel.

In aspects, the screw member defines a distal cutting tip. The screw member may additionally or alternatively include one or more proximally-facing barbs.

In aspects, the screw member includes first and second screw arms. Each screw arm defines a helical configuration.

In aspects, the screw member includes a support plate secured to the exterior of the screw member and extending longitudinally along the screw member. The support plate is configured to maintain a fixed axial length of the screw member.

In aspects, the support plate defines sharpened longitudinal edges to facilitate cutting tissue.

In aspects, the support plate is affixed to at least two different turns of the screw member.

In aspects, the sensor assembly includes a sensor housing enclosing the at least one location sensor therein. The sensor housing may be rigid.

In aspects, a sheath is slidably disposed about the elongated flexible body and is movable between an extended position, wherein the sheath extends distally at least to a distal end of the screw member, and a retracted position, wherein the sheath is positioned proximally of the screw member to expose the screw member.

In aspects, the at least one location sensor includes a plurality of sensor components configured to enable detection of the location of the sensor assembly in six degrees of freedom, although other sensor configurations are also contemplated.

In aspects, the elongated flexible body includes an outer member and an inner member disposed within the outer member. The outer member is rotatable about and relative to the inner member and defines a distal end that extends beyond a distal end of the inner member. In such aspects, the sensor assembly is engaged to the distal end of the inner member, extends distally from the inner member, and is disposed within the outer member. Further, in such aspects,

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the screw member is engaged to the distal end of outer member and extends distally from the outer member such that rotation of the outer member effects rotation of the screw member relative to the inner member and the sensor assembly.

BRIEF DESCRIPTION OF THE DRAWINGS

Various aspects and features of the present disclosure are described hereinbelow with references to the drawings, wherein:

FIG. 1 is a perspective view of a system provided in accordance with the present disclosure configured for navigating a biopsy tool to a target location and obtaining a tissue sample using the biopsy tool;

FIG. 2 is a side view of the distal end of the biopsy tool of FIG. 1 with the sheath disposed in the retracted position

FIG. 3 is a side, cross-sectional view of the distal end of the biopsy tool of FIG. 1 with the sheath removed therefrom;

FIG. 4A is a side view of the proximal end of the biopsy tool of FIG. 1 illustrating the proximal handle portion thereof;

FIG. 4B is a side view of the proximal end of the biopsy tool of FIG. 1 including another embodiment of a proximal handle portion coupled thereto;

FIGS. 5A-5D progressively illustrate use of the biopsy tool of FIG. 1 for obtaining a tissue sample;

FIG. 6 is a perspective view of a sensor configured for use with the biopsy tool of FIG. 1;

FIG. 7 is a perspective view of another sensor configured for use with the biopsy tool of FIG. 1;

FIG. 8 is a perspective view of another sensor configured for use with the biopsy tool of FIG. 1;

FIG. 9 is an exploded, perspective view of a transmitter mat configured for use with the system of FIG. 1 for tracking the biopsy tool through a patient's airways

FIG. 10A is a first side view of another embodiment of a screw member configured for use with the biopsy tool of FIG. 1;

FIG. 10B is a second side view of the screw member of FIG. 10A wherein the screw member is shown rotated 90 degrees from the position of FIG. 10A; and

FIG. 11 is a side view of another embodiment of a screw member configured for use with the biopsy tool of FIG. 1.

DETAILED DESCRIPTION

Devices, systems, and methods for navigating a biopsy tool to a target location and obtaining a tissue sample using the biopsy tool are provided in accordance with the present disclosure and described in detailed below. The biopsy tool of the present disclosure, for example, generally includes a flexible body, a screw disposed at the distal end of the flexible body, and a sensor assembly integrated into the biopsy tool and positioned proximally adjacent the screw. The screw defines a helical configuration having a hollow interior and is configured for simultaneous rotation relative to tissue and advancement into tissue to obtain a tissue sample. The sensor assembly enables determination of the current location of the screw, thus facilitating navigation of the screw to target tissue and/or manipulation of the screw relative to target tissue. Detailed embodiments of such devices, systems incorporating such devices, and methods using the same as described below. However, these detailed embodiments are merely examples of the disclosure, which may be embodied in various forms. Therefore, specific structural and functional details disclosed herein are not to

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be interpreted as limiting, but merely as a basis for the claims and as a representative basis for allowing one skilled in the art to variously employ the present disclosure in virtually any appropriately detailed structure.

With reference to FIG. 1, a system provided in accordance with the present disclosure and configured for planning a pathway to target tissue (planning phase), navigating a positioning assembly to the target tissue (navigation phase), and navigating a biopsy tool to the target tissue to obtain a tissue sample from the target tissue using the biopsy tool (biopsy phase) is shown generally identified by reference numeral 10. System 10 generally includes an operating table 40 configured to support a patient "P;" a bronchoscope 50 configured for insertion through the patient's mouth into the patient's airways; monitoring equipment 60 coupled to bronchoscope 50 for displaying video images received from bronchoscope 50; a tracking system 70 including a tracking module 72, a plurality of reference sensors 74, and a transmitter mat 76; a computer 80 including software and/or hardware used to facilitate pathway planning, identification of target tissue, and navigation to target tissue; a positioning assembly 90 including an LG 92 and an EWC 96; and a biopsy tool 100 operable to obtain a tissue sample, e.g., for subsequent diagnostic testing. The planning and navigation phases will initially be detailed below, followed by a detailed description of biopsy tools provided in accordance with the present disclosure and use of such biopsy tools in conjunction with system 10 in performing the biopsy phase.

With respect to the planning phase, computer 80 utilizes computed tomographic (CT) image data for generating and viewing a three-dimensional model of the patient's airways, enables the identification of target tissue on the three-dimensional model (automatically, semi-automatically or manually), and allows for the selection of a pathway through the patient's airways to the target tissue. More specifically, the CT scans are processed and assembled into a three-dimensional CT volume, which is then utilized to generate a three-dimensional model of the patient's airways. The three-dimensional model may be displayed on a display monitor associated with computer 80, or in any other suitable fashion. Using computer 80, various views of the three-dimensional model may be provided and/or the three-dimensional model may be manipulated to facilitate identification of target tissue on the three-dimensional model and selection of a suitable pathway through the patient's airways to access the target tissue. Once selected, the pathway is saved for use during the navigation phase(s).

Continuing with reference to FIG. 1, patient "P" is shown lying on operating table 40 with bronchoscope 50 inserted through the patient's mouth and into the patient's airways. Bronchoscope 50 includes a source of illumination and a video imaging system (not explicitly shown) and is coupled to monitoring equipment 60, e.g., a video display, for displaying the video images received from the video imaging system of bronchoscope 50.

With respect to the navigation phase, a six degrees-of-freedom electromagnetic tracking system 70, e.g., similar to those disclosed in U.S. Pat. No. 6,188,355 and published PCT Application Nos. WO 00/10456 and WO 01/67035, the entire contents of each of which is incorporated herein by reference, or other suitable positioning measuring system, is utilized for performing registration and navigation, although other configurations are also contemplated. Tracking system 70 includes a tracking module 72, a plurality of reference sensors 74, and a transmitter mat 76. Tracking system 70 is configured for use with positioning assembly 90 and biopsy tool 100, as detailed below. Positioning assembly 90

includes a LG 92 having a steerable distal tip 93 incorporating a sensor 94, an EWC 96, and a handle 98. LG 92 and EWC 96 are configured for insertion through a working channel of bronchoscope 50 into the patient's airways (although LG 92 and EWC 96 may alternatively be used without bronchoscope 50) and are selectively lockable relative to one another via a locking mechanism 99. Steerable distal tip 93 of LG 92 may be configured for steering in any suitable fashion, e.g., using a plurality of steering wires (not shown) coupled between handle 98 and distal tip 93, to facilitate maneuvering distal tip 93 of LG 92 and EWC 96 through the patient's airways. Distal tip 93 of LG 92 may further define, at-rest, a linear, curved, or angled configuration, depending on a particular purpose. Sensor 94 is integrated with distal tip 93 of LG 92 and allows monitoring of the position and orientation of distal tip 93, in six degrees of freedom, relative to the reference coordinate system. Sensor 94 of LG 92 may be configured similar to any of the sensors detailed below with respect to biopsy tool 100 (see FIGS. 6-8).

As shown in FIG. 1, transmitter mat 76 is positioned beneath patient "P." The internal configuration of transmitter mat 76 will be detailed below with reference to FIG. 9. Transmitter mat 76 and the plurality of reference sensors 74 are interconnected with tracking module 72, which derives the location of each sensor 74 in six degrees of freedom. One or more of reference sensors 74 are attached to the chest of the patient "P." The six degrees of freedom coordinates of reference sensors 74 are sent to computer 80 (which includes the appropriate software) where they are used to calculate a patient coordinate frame of reference. Registration, as detailed below, is generally performed by identifying locations in both the three-dimensional model and the patient's airways and measuring the coordinates in both systems. Further details of such a registration technique can be found in U.S. Patent Application Pub. No. 2011/0085720, the entire contents of which is incorporated herein by reference, although other suitable registration techniques are also contemplated. An exemplary embodiment of a transmitter mat 76, and the use thereof for determining location data, is detailed below.

In use, with respect to the navigation phase, LG 92 is inserted into EWC 96 such that sensor 94 projects from the distal end of EWC 96. LG 92 and EWC 96 are then locked together via locking mechanism 99. LG 92, together with EWC 96, are then inserted through bronchoscope 50 and into the airways of the patient "P," with LG 92 and EWC 96 moving in concert with one another through bronchoscope 50 and into the airways of the patient "P." Automatic registration is performed by moving LG 92 through the airways of the patient "P." More specifically, data pertaining to locations of sensor 94 while LG 92 is moving through the airways is recorded using transmitter mat 76, reference sensors 74, and tracking module 72. A shape resulting from this location data is compared to an interior geometry of passages of the three-dimensional model generated in the planning phase, and a location correlation between the shape and the three-dimensional model based on the comparison is determined, e.g., utilizing the software on computer 80. In addition, the software identifies non-tissue space (e.g., air filled cavities) in the three-dimensional model. The software aligns, or registers, an image representing a location of sensor 94 of LG 92 with an image of the three-dimensional model based on the recorded location data and an assumption that LG 92 remains located in non-tissue space in the patient's airways. This completes the registration portion of the navigation phase.

Referring still to FIG. 1, once the planning phase has been completed, e.g., the target tissue has been identified and the pathway thereto selected, and registration has been completed, system 10 may be utilized to navigate LG 92 through the patient's airway to the target tissue. To facilitate such navigation, computer 80, monitoring equipment 60, and/or any other suitable display may be configured to display the three-dimensional model including the selected pathway from the current location of sensor 94 of LG 92 to the target tissue. Navigation of LG 92 to the target tissue using tracking system 70 is similar to that detailed below with respect to the navigation of biopsy tool 100 to the target tissue and, thus, is not detailed here for purposes of brevity.

Once LG 92 has been successfully navigated to the target tissue, completing the navigation phase, LG 92 may be unlocked from EWC 96 and removed, leaving EWC 96 in place as a guide channel for guiding biopsy tool 100 to the target tissue. Details of biopsy tool 100, along with the use of the same in the biopsy phase, are described below.

Referring now to FIGS. 2-4A, in conjunction with FIG. 1, as mentioned above, biopsy tool 100 is provided in accordance with the present disclosure for obtaining a tissue sample from the target tissue. As detailed below, biopsy tool 100 is further configured for use in conjunction with tracking system 70 to facilitate navigation of biopsy tool 100 to the target tissue and/or tracking of biopsy tool 100 as it is manipulated relative to the target tissue to obtain the tissue sample. Although registration and navigation are detailed above with respect to LG 92 of positioning assembly 90, it is also envisioned that LG 92 be eliminated and biopsy tool 100 itself be utilized for registration and navigation, similarly as detailed above with respect to LG 92. Biopsy tool 100 generally includes a biopsy assembly 110 and a sheath assembly 150 slidably disposed about biopsy assembly 110. However, in some embodiments, sheath assembly 150 need not be provided but, rather EWC 96 (FIG. 1) may serve the function of sheath assembly 150. Biopsy assembly 110 includes a proximal handle portion 120, an elongated flexible body portion 130, and a rigid distal end portion 140. As shown in FIG. 4, proximal handle portion 120 includes a housing 122 that encloses the inner operating components of biopsy assembly 110, e.g., battery 123 and drive motor 124. Housing 122 may further be configured to house a memory (e.g., an EEPROM) storing a variety of information regarding biopsy tool 100. For example, the memory may include identification information that can be used by the drive motor 124 to ensure that only properly identified biopsy tools 100 are connected thereto, e.g., in embodiments where proximal handle portion 120 is detachable from elongated flexible body portion 130 and/or rigid distal end portion 140. In addition, the memory may store operating parameters of the biopsy tool 100, e.g., power, time, RPM limits, and information regarding the usage of biopsy tool 100. Usage monitoring may enable limiting re-use of biopsy tool 100 beyond a certain number of activations, amount of activation time, or may limit biopsy tool 10 to a single use. Such usage limitations may optionally be reset via reprocessing as is commonly understood in the art.

An actuator 125 is operably coupled to housing 122 at the proximal end thereof and is selectively actuatable to activate drive motor 124, e.g., by completing a circuit including battery 123 and drive motor 124, to drive rotation of biopsy assembly 110, as detailed below. Alternatively, biopsy assembly 110 may be configured to connect to a remote drive and/or power source, or may be manually driven. A selection switch (not shown) operably coupled to drive motor 124 may also be provided for allowing a user to select

a direction of rotation of biopsy assembly 110, e.g., to effect either clockwise or counter-clockwise rotation of biopsy assembly 110.

Body portion 130 of biopsy assembly 110 is coupled to and extends distally from proximal handle portion 120. More specifically, body portion 130 includes an outer member 132 that is coupled to drive motor 124 and rotatably engaged to housing 122, and an inner member 134 that extends through outer member 132 and is engaged to housing 122. Both of outer and inner members 132, 134 are flexible to permit insertion of body portion 130 through a patient's airways, and are rotatable relative to one another, e.g., outer member 132 is rotatable about inner member 134 relative to housing 122 upon activation of drive motor 124. As shown in FIG. 3, the distal end of outer member 132 extends distally beyond the distal end of inner member 134. Alternatively, inner member 134 need not be provided, or inner member 134 may be configured to rotate relative to housing 122 while outer member 132 is fixed relative to housing 122.

Referring to FIGS. 2 and 3, distal end portion 140 of biopsy assembly 110 is disposed at the distal end of elongated flexible body portion 130 and includes a screw member 142 and a sensor assembly 145. Screw member 142 is fixedly engaged to the distal end of outer member 132 such that rotation of outer member 132 effects similar rotation of screw member 142. Screw member 142 is rigidly formed from stainless steel or other suitable material and defines a helical configuration having a hollow interior 143 configured to receive and retain a tissue sample, as detailed below. Screw member 142 further defines a pointed distal tip 144a and a plurality of proximally-facing barbs 144b. Distal tip 144a facilitates advancement of screw member 142 through tissue and about the tissue sample, while proximally-facing barbs 144b facilitate coring of tissue about the tissue sample.

Sensor assembly 145, as shown in FIG. 3, includes a sensor housing 146 engaged to the distal end of inner member 134. Since the distal end of outer member 132 extends distally beyond the distal end of inner member 134, sensor housing 146 is disposed within outer member 132, proximally of screw member 142. In embodiments where inner member 134 is not provided, sensor assembly 145 may be engaged within outer member 132 toward the distal end thereof and proximally of screw member 142. Sensor housing 146 encloses a sensor 148 therein and is rigidly formed from any suitable material that does not interfere with the operation of sensor 148. Sensor 148, in conjunction with tracking system 70 (FIG. 1), enables tracking of distal end portion 140 of biopsy assembly 110 as distal end portion 140 is advanced through the patient's airways, as detailed below. Thus, with additional reference to FIG. 1, computer 80, monitoring equipment 60, and/or any other suitable display may be configured to display the three-dimensional model and selected pathway, both of which were generated during the planning phase, along with the current location of sensor 148 of distal end portion 140 to facilitate navigation of distal end portion 140 to the target tissue and/or manipulation of distal end portion 140 relative to the target tissue. Various sensors 148 suitable for use with biopsy assembly 110 for this purpose are detailed below (see FIGS. 6-8).

Sheath assembly 150, as best shown in FIGS. 2 and 4A, includes an elongated sheath 160 and a slider 170 engaged to sheath 160 at the proximal end of sheath 160. Sheath 160 is slidably disposed about distal end portion 140 and body portion 130 of biopsy assembly 110 and may be dimensioned to generally approximate the outer radial dimension of distal end portion 140 of biopsy assembly 110, such that

biopsy tool 100 defines a low profile configuration. Sheath 160 is movable relative to biopsy assembly 110 between an extended position (FIGS. 1 and 5A), wherein sheath 160 extends to or beyond the distal end of biopsy assembly 110 to protect biopsy assembly 110 and inhibit damage with distal end portion 140 during insertion of biopsy tool 100 through bronchoscope 50, EWC 96 and/or the patient's airways to the target tissue, and a retracted position (FIGS. 2 and 5B-5D), wherein sheath 160 is retracted to expose screw member 142 of distal end portion 140 of biopsy assembly 110. As an alternative to extension and retraction, sheath assembly 150 may be configured to be fully withdrawn from about biopsy assembly 110 once biopsy assembly 110 is positioned as desired.

With reference FIG. 4A, slider 170 is slidably disposed about housing 122 of proximal handle portion 120 of biopsy assembly 110 and, as mentioned above, is engaged to the proximal end of sheath 160. Slider 170 is selectively slidable about housing 122 to move sheath 160 between the extended position and the retracted position. A locking mechanism (not shown) may also be provided for selectively locking slider 170 in the extended and/or retracted position.

With momentary reference to FIG. 4B, as an alternative to being powered or motor-driven, biopsy assembly 110 may be additionally or alternatively configured for use with a manually-drive proximal handle portion 120'. Proximal handle portion 120' includes a housing 122' having a manually manipulatable element 124' rotatably coupled to housing 122' and operably engaged to outer member 132 for manually driving rotation of biopsy assembly 110. More specifically, upon manual rotation of element 124' relative to housing 122', outer member 132 is similarly rotated to thereby effect similar rotation of screw member 142 (FIGS. 2-3) to advance screw member 142 (FIGS. 2-3) through tissue and about a tissue sample.

Turning now to FIGS. 5A-5D, in conjunction with FIG. 1, the use of biopsy tool 100 for obtaining a tissue sample (the biopsy phase) is described. Once the planning and navigation phases have been completed, and LG 92 removed from EWC 96, biopsy tool 100, with sheath 160 disposed in the extended position, may be inserted through bronchoscope 50 and EWC 96, to the target tissue. Sensor 148 of biopsy tool 100, in conjunction with tracking system 70, as mentioned above, enable tracking of sensor 148 as it is advanced through the patient's airways. Thus, even after distal end portion 140 is extended distally from EWC 96, the position of distal end portion 140 can be tracked, thus permitting navigation of screw member 142 to and/or manipulation of screw member 142 relative to the target tissue to ensure proper positioning of screw member 142 relative to the target tissue and allowing certain tissue structures adjacent the target tissue to be avoided. Tracking and navigating using sensor 148 and tracking system 70 will be described in greater detail below, following the description of the various embodiments thereof.

Referring to FIG. 5A, once distal end portion 140 of biopsy assembly 110 is positioned as desired, sheath 160 may be moved from the extended position to the retracted position, e.g., via sliding slider 170 proximally about housing 122 (FIG. 4A), to expose screw member 142. Turning to FIGS. 5B-5D, with screw member 142 exposed and positioned adjacent the target tissue, screw member 142 may be activated, e.g., by actuating actuator 125 to activate drive motor 124 to drive rotation of outer member 132 and, thus, screw member 142. More specifically, screw member 142 may be activated to rotate in a first direction such screw member 142 is lead by distal tip 144a during advancement

into tissue. Sensor assembly **145** (FIG. 3), which is engaged to inner member **134**, is not rotated in conjunction with screw member **142** but, rather, as mentioned above, screw member **142** and outer member **132** are rotated about and relative to inner member **134** and, thus sensor assembly **145**. As such, the orientation and position of sensor **148** (FIG. 3) can still be readily determined and displayed to the operator, even while screw member **142** is actively rotating. Alternatively, as mentioned above, inner member **134** need not be provided and sensor assembly **145** may be engaged within outer member **132** such that sensor assembly **145** is rotated therewith.

Continuing with reference to FIGS. 5B-5D, with screw member **142** activated, e.g., rotating relative to the target tissue in the first direction, screw member **142** may be advanced into the target tissue such that a tissue sample is received within hollow interior **143** of screw member **142** while distal tip **144a** and proximally-facing barbs **144b** facilitate coring of tissue about the tissue sample. Sensor **148** (FIG. 3) enables the tracking of screw member **142** during tissue sampling such that the surgeon can readily ascertain the depth of screw member **142** relative to tissue, the angle of insertion, etc., thus helping to ensure a suitable tissue sample is obtained with minimal tissue damage. Although sensor **148** (FIG. 3) is displaced from screw member **142**, the construction of distal end portion **140** of biopsy assembly **110** enables accurate determination of the positioning of screw member **142** within the patient's airways and relative to the target tissue. In fact, the software of computer **80** (FIG. 1) may be configured to provide for the display of screw member **142** based upon the location data of sensor **148** (FIG. 3) received from tracking system **70** (FIG. 1), as screw member **142** is disposed at a fixed distance and angle relative to sensor **148** (FIG. 3), although the rotational orientation of screw member **142** relative to sensor **148** (FIG. 3) is variable.

Once a sufficient tissue sample has been received and retained within hollow interior **143** of screw member **142**, actuator **125** (FIG. 4A) may be released (or otherwise returned to an un-actuated position), to deactivate drive motor **124** (FIG. 4A) and stop rotation of outer member **132** and screw member **142**. Additionally, where advantageous, drive motor **124** (FIG. 4A) may be activated to rotate in a second, opposite direction at this point to facilitate shearing or coring about the tissue sample with barbs **144b** to ensure full separation of the tissue sample from the target location and retention of the tissue sample within hollow interior **143**. Thereafter, biopsy tool **100** may be withdrawn from the patient's airways, EWC **96**, and bronchoscope **50** (FIG. 1) and the tissue sample retrieved therefrom for diagnostic testing or other purposes. Sheath **160** may be returned to the extended position prior to withdrawal, or may be left in the retracted position during withdrawal of biopsy tool **100**.

Turning now to FIGS. 6-8, in conjunction with FIG. 1, various different sensors **248**, **348**, **448** (FIGS. 6-8, respectively) configured for use as sensor **148** of sensor assembly **145** of biopsy tool **100** (see FIG. 3), and/or sensor **94** of LG **92** are described. Referring to FIG. 6, sensor **248** is shown. Sensor **248** includes a plurality of field component sensor elements **251a**, **251b**, **1252a**, **252b**, **253**. Each sensor element **251a**, **251b**, **252a**, **252b**, **253** is formed as a coil and arranged for sensing a different component of an electromagnetic field generated by transmitter mat **76** (FIG. 9). More specifically, first and second pairs of sensor elements **251a**, **251b** and **252a**, **252b** are arranged within sensor housing **246** such that the respective elements **251a**, **251b** and **252a**, **252b** of each pair are equidistant from a common

reference point **254**, while sensor element **253** is centered about reference point **254**. Although shown in FIG. 6 as collinearly disposed, other configurations of sensor elements **251a**, **251b**, **1252a**, **252b**, **253** are also contemplated. Further, as opposed to providing five sensor elements **251a**, **251b**, **1252a**, **252b**, **253** wherein sensor element **253** is centered about the reference point **254**, six sensors may be provided, e.g., wherein sensor element **253** is provided as a pair of elements disposed equidistant from reference point **254**. The above-described configuration of sensor **248** enables transmitter mat **76** and the plurality of reference sensors **74** (FIG. 1), together with tracking module **72** and computer **80** (FIG. 1), to derive the location of sensor **248** in six degrees of freedom, as detailed below, and as further detailed in U.S. Pat. No. 6,188,355 and published PCT Application Nos. WO 00/10456 and WO 01/67035, previously incorporated herein by reference.

With reference to FIG. 7, sensor **348** is shown including two sensor components **351**, **353** arranged within sensor housing **346**, each component **351**, **353** including three sensor elements **352a**, **352b**, **352c** and **354a**, **354b**, **354c**, respectively. Each sensor element **352a**, **352b**, **352c** and **354a**, **354b**, **354c** is configured as a flat rectangular coil, e.g., including a plurality of turns of conducting wire, bent to define an arcuate shape. As such, the elements **352a**, **352b**, **352c** and **354a**, **354b**, **354c** combine to define first and second generally cylindrical components **351**, **353**. Components **351**, **353** are centered about reference axis **356** and positioned such that each of elements **352a**, **352b**, **352c** and **354a**, **354b**, **354c** are equidistant from reference axis **356** and such that each of elements **352a**, **352b**, **352c** of component **351** are oriented 180 degrees offset as compared to corresponding elements **354a**, **354b**, **354c**, respectively, of component **353**. Thus, similarly as with sensor **248** (FIG. 6), sensor **348** enables transmitter mat **76** and the plurality of reference sensors **74** (FIG. 1), together with tracking module **72** and computer **80** (FIG. 1), to derive the location of sensor **348** in six degrees of freedom.

Turning to FIG. 8, sensor **448** includes three coils **451**, **452**, **453**. Coils **451** and **452**, **453** are angled relative to housing **446**, while coil **453** is circumferentially disposed within housing **446**. Coils **451**, **452**, **453** are oriented to lie in perpendicular planes relative to one another and share a common center reference point **454**. By sharing a common center reference point **454**, each portion of each coil **451**, **452**, **453** is equidistant from center reference point **454**. Further, this configuration, e.g., wherein coils share a common center reference point **454** rather than being longitudinally displaced relative to one another, allows for the longitudinal dimension of sensor **448** to be minimized. Such a configuration still, however, enables transmitter mat **76** and the plurality of reference sensors **74** (FIG. 1), together with tracking module **72** and computer **80** (FIG. 1), to derive the location of sensor **448** in six degrees of freedom.

Referring to FIG. 9, in conjunction with FIG. 1, an embodiment of the internal configuration of transmitter mat **76** of tracking system **70** (FIG. 1) is shown, although other suitable configurations are also contemplated. Transmitter mat **76** is a transmitter of electromagnetic radiation and includes a stack of three substantially planar rectangular loop antennas **77a**, **77b**, **77c** configured to connected to drive circuitry (not shown).

Antenna **77a** is skewed in a first horizontal direction (when the transmitter mat **76** is horizontal) in that the loops on one side of the antenna **77a** are closer together than the loops on the opposite side. As a result, antenna **77a** creates a magnetic field that is stronger on the side where the loops

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are close together than on the opposite side. By measuring the strength of the current induced by antenna **77a** in the sensor assembly, e.g., sensor assembly **145** of biopsy tool **100** (FIG. **3**) or sensor **94** of LG **92** (FIG. **1**), it can be determined where the sensor assembly is located in the first direction over antenna **77a**.

Antenna **77b** is similar to antenna **77a** except that antenna **77b** is skewed in an second horizontal direction that is perpendicular to the first direction. By measuring the strength of the current induced by antenna **77b** in the sensor assembly, it can be determined where the sensor assembly is located in the second direction over antenna **77b**.

Antenna **77c** defines a uniform, i.e., un-skewed, configuration. Thus, antenna **77c** creates a uniform field that naturally diminishes in strength in a vertical direction when the transmitter mat **76** is horizontal. By measuring the strength of the field induced in the sensor assembly, it can be determined how far the sensor assembly is located above antenna **77c**.

In order to distinguish one magnetic field from another, the fields of antennae **77a**, **77b**, **77c** are generated using independent frequencies. For example, antenna **77a** may be supplied with alternating current oscillating at 2.5 kHz, antenna **77b** may be supplied with alternating current oscillating at 3.0 kHz, and antenna **77c** may be supplied with alternating current oscillating at 3.5 kHz, although other configurations are also contemplated. As a result of using independent frequencies, each of the sensor components of the sensor assembly (see FIGS. **6-8**, for example) will have a different alternating current signal induced in its coils.

Referring additionally to FIG. **1**, in use, signal generators and amplifiers of the driving circuitry (not shown) associated with tracking system **70** are utilized to drive each of antennae **77a**, **77b**, **77c** of transmitter mat **76** at their corresponding frequencies. The electromagnetic waves generated by transmitter mat **76** are received by the various sensor elements of the sensor assembly e.g., the sensor elements of sensors **248**, **348**, **448** (FIGS. **6-8**, respectively) configured for use with sensor assembly **145** of biopsy tool **100** (FIG. **3**) or sensor **94** of LG **92**, and are converted into electrical signals that are sensed via reference sensors **74**. Tracking system **70** further includes reception circuitry (not shown) that has appropriate amplifiers and A/D converters that are utilized to receive the electrical signals from reference sensors **74** and process these signals to determine and record location data of the sensor assembly. Computer **80** may be configured to receive the location data from tracking system **70** and display the current location of the sensor assembly on the three-dimensional model and relative to the selected pathway generated during the planning phase, e.g., on computer **80**, monitoring equipment **60**, or other suitable display. Thus, navigation of biopsy tool **100** (FIG. **3**) and/or LG **92** to the target tissue and/or manipulation of biopsy tool **100** (FIG. **3**) relative to the target tissue, as detailed above, can be readily achieved.

FIGS. **10A-10B** illustrates another embodiment of a screw member **1142** configured for use with biopsy assembly **110** (FIGS. **1-5D**). Screw member **1142** is similar to screw member **142** (FIGS. **2-3**) and, thus, only the differences therebetween will be described in detail below for purposes of brevity.

Screw member **1142** is configured for fixed engagement to the distal end of outer member **132** (FIGS. **2-3**) such that rotation of outer member **132** (FIGS. **2-3**) effects similar rotation of screw member **1142**. Screw member **1142** defines a helical configuration having a hollow interior **1143** configured to receive and retain a tissue sample, a pointed distal

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tip **1144a**, and a plurality of proximally-facing barbs **1144b**. Screw member **1142** further includes a support plate **1146** secured to, e.g., via welding or other suitable method, the exterior surface of screw member **1142** and extending longitudinally therealong. More specifically, support plate **1146** is secured to a plurality of "turns" of the helical-shaped screw member **1142** so as to inhibit axial contraction of screw member **1142**, e.g., during insertion of screw member **1142**, and axial expansion of screw member **1142**, e.g., during withdrawal of screw member **1142**. Support plate **1146** further includes sharpened longitudinal edges **1147** configured to facilitate the coring of tissue about the tissue sample as screw member **1142** is advanced into tissue. Screw member **1142** may otherwise be configured similarly to or include any of the features of screw member **142** (FIGS. **2-3**), and vice versa.

Referring to FIG. **11**, another embodiment of a screw member **2142** configured for use with biopsy assembly **110** (FIGS. **1-5D**) is shown. Screw member **2142** is similar to screw member **142** (FIGS. **2-3**) except that screw member **2142** defines a double-helix configuration having first and second screw arms **2144**, **2146**. Each screw arm **2144**, **2146** includes a pointed distal end **2145**, **2147** and may include any of the features of screw member **142** (FIGS. **2-3**) and/or screw member **1142** (FIGS. **10A-10B**). The double-helix configuration of screw member **2142** provides two "starts," e.g., at pointed distal ends **2145**, **2147** of arms **2144**, **2146**, respectively, to facilitate initiation of tissue coring as screw member **2142** is initially advanced into tissue. This configuration also provide increased cutting surface area (as there are two arms as opposed to one) to facilitate coring of tissue during advancement of screw member **2142** through tissue and enables each arm to have a relatively greater pitch length while still providing a sufficient cutting effect.

While several embodiments of the disclosure have been shown in the drawings, it is not intended that the disclosure be limited thereto, as it is intended that the disclosure be as broad in scope as the art will allow and that the specification be read likewise. Therefore, the above description should not be construed as limiting, but merely as exemplifications of particular embodiments. Those skilled in the art will envision other modifications within the scope and spirit of the claims appended hereto.

What is claimed is:

1. A biopsy tool, comprising:
a handle:

an elongated flexible body having a proximal portion coupled to a distal portion of the handle, wherein the proximal portion is releasably coupled to the handle, the elongated flexible body defining a distal end;

a sensor assembly disposed within the elongated flexible body towards the distal end thereof and including at least one location sensor configured to enable detection of a location of the sensor assembly within a patient's airways; and

a screw member directly coupled to the distal end of the elongated flexible body and extending distally from the elongated flexible body, the screw member positioned distally of the sensor assembly, the screw member defining a helical configuration having a hollow interior and configured for simultaneous rotation relative to tissue and advancement into tissue to obtain a tissue sample within the hollow interior.

2. The biopsy tool according to claim 1, wherein the handle including a housing having a drive motor disposed within the housing, the drive motor configured to rotate the screw member.

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3. The biopsy tool according to claim 2, wherein the handle further includes an actuator configured for selectively activating the drive motor.

4. The biopsy tool according to claim 3, wherein the handle further includes a battery disposed within the housing, and where actuation of the actuator completes an electrical circuit between the battery and the drive motor to activate the drive motor.

5. The biopsy tool according to claim 1, wherein the handle is configured for manual manipulation to drive rotation of the screw member.

6. The biopsy tool according to claim 1, wherein the screw member is rigid.

7. The biopsy tool according to claim 6, wherein the screw member is made of stainless steel.

8. The biopsy tool according to claim 1, wherein the screw member defines a distal cutting tip.

9. The biopsy tool according to claim 1, wherein the screw member includes at least one proximally-facing barb.

10. The biopsy tool according to claim 1, wherein the screw member includes first and second screw arms, each screw arm defining a helical configuration.

11. The biopsy tool according to claim 1, wherein the sensor assembly includes a sensor housing, the sensor housing enclosing the at least one location sensor therein.

12. The biopsy tool according to claim 11, wherein the sensor housing is rigid.

13. The biopsy tool according to claim 1, further comprising a sheath slidably disposed about the elongated flexible body and movable between an extended position, wherein the sheath extends distally at least to a distal end of the screw member, and a retracted position, wherein the sheath is positioned proximally of the screw member to expose the screw member.

14. The biopsy tool according to claim 1, wherein the at least one location sensor includes a plurality of sensor components configured to enable detection of the location of the sensor assembly in six degrees of freedom.

15. The biopsy tool according to claim 9, wherein the at least one proximally-facing barb is spaced-apart from a distal end of the screw member.

16. A biopsy tool, comprising:
 an elongated flexible body defining a distal end;
 a sensor assembly disposed within the elongated flexible body towards the distal end thereof and including at least one location sensor configured to enable detection of a location of the sensor assembly within a patient's airways; and

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a screw member coupled to the distal end of the elongated flexible body and extending distally from the elongated flexible body, the screw member positioned distally of the sensor assembly, the screw member defining a helical configuration having a hollow interior and configured for simultaneous rotation relative to tissue and advancement into tissue to obtain a tissue sample within the hollow interior, the screw member including a support plate secured to an exterior surface of the screw member and extending longitudinally along the screw member, the support plate configured to maintain a fixed axial length of the screw member.

17. The biopsy tool according to claim 16, wherein the support plate defines sharpened longitudinal edges to facilitate cutting tissue.

18. The biopsy tool according to claim 16, wherein the support plate is affixed to at least two different turns of the screw member.

19. A biopsy tool, comprising:
 an elongated flexible body defining a distal end;
 a sensor assembly disposed within the elongated flexible body towards the distal end thereof and including at least one location sensor configured to enable detection of a location of the sensor assembly within a patient's airways; and

a screw member coupled to the distal end of the elongated flexible body and extending distally from the elongated flexible body, the screw member positioned distally of the sensor assembly, the screw member defining a helical configuration having a hollow interior and configured for simultaneous rotation relative to tissue and advancement into tissue to obtain a tissue sample within the hollow interior,

wherein the elongated flexible body includes an outer member and an inner member disposed within the outer member, the outer member is configured to rotate about and relative to the inner member and defining a distal end that extends beyond a distal end of the inner member,

wherein the sensor assembly is engaged to the distal end of the inner member, extends distally from the inner member, and is disposed within the outer member, and wherein the screw member is engaged to the distal end of the outer member and extends distally from the outer member such that rotation of the outer member effects rotation of the screw member relative to the inner member and the sensor assembly.

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